Office Action Summary	Application No.	Applicant(s)	
	10/567,630	ALITALO ET AL.	
	Examiner	Art Unit	
	STEPHEN KAPUSHOC	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15 and 79* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 February 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *20100112*.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1-15,17,21,22,25-29,31,33,34,36-38,41,46,48,52,54,55,68,70-76 and 79.
Continuation of Disposition of Claims: Claims withdrawn from consideration are 17,21,22,25-29,31,33,34,36-38,41,46,48,52,54,55,68 and 70-76.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :12/18/06; 02/20/07; 06/26/08; 01/19/09; 04/10/09.

DETAILED ACTION

Claims 1-15, 17, 21, 22, 25-29, 31, 33, 34, 36-38, 41, 46, 48, 52, 54, 55, 68, 70-76 and 79 are pending.

Claims 17, 21, 22, 25-29, 31, 33, 34, 36-38, 41, 46, 48, 52, 54, 55, 68 and 70-76 are withdrawn from examination as detailed below.

Claims 1-15 and 79 are examined on the merits.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-15 and 79, drawn to methods of diagnosing a pathological condition.

Group 2, claim(s) 17, 21, 22, 25-29, 31, 33, 34, 36-38, 41, 46, 68 and 70-76, drawn to treatment methods requiring suppression of the expression or activity of Prox-1.

Group 3, claim(s) 48, 52, 54 and 55, drawn to methods for identification of modulators of Prox-1.

2. The inventions listed as Groups 1-3 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The different groups lack a common technical feature because they are different in their required methodological steps and the functions performed by the methods as claimed. The methods of Group 1 require quantitative analytical measurements of prox-1 expression or activity in order to diagnose a pathological condition, whereas the methods of Group 2 require administration of compounds with known activities (i.e. prox-1 inhibition) for the treatment of a pathology, and the methods of Group 3 requirement a qualitative measurement of biomolecule interactions in order to identify a

compound with a potential activity (i.e. modulation of Prox-1). As such there is not a corresponding special technical feature among the three different groups.

It is noted that if Applicants assert that a special technical feature among the different groups is the prox-1 gene, or the role of prox-1 expression in cell proliferation, both the gene and its role in cell proliferation were known in the art at the time the invention was made. See for Example Parr et al (International Journal of Oncology (2003) vol. 23 p.533-539), as cited in this Office Action. As such this feature would not be considered a special technical feature in view of the prior art.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Molecules that suppress prox-1: (i) antisense oligonucleotides; (ii) inhibitory RNAs; (iii) inhibitory zinc finger proteins; (iv) dominant negative prox 1; of (v) nucleic acids encoding dominant negative prox 1.

Methods for screening requiring: (i) prox 1 expression; or (ii) prox 1 activity.

Methods to measure the B-catenin/TCF pathway requiring: (i) APC gene mutations; (ii) B-catenin gene mutations; or (iii) nuclear localization of B-catenin.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. The claims are deemed to correspond to the species listed above in the following manner:

Molecules that suppress prox-1: (i) antisense oligonucleotides (claim 22 in part, claim 68 and 70-76); (ii) inhibitory RNAs (claim 22 in part, claim 25 and 70); (iii) inhibitory zinc finger proteins (claim 26); (iv) dominant negative prox 1protein and nucleic acids encoding dominant negative prox 1 (claims 27-29).

Methods for screening requiring: (i) prox 1 expression (claims 1-5 and 79 in part as they recite expression); or (ii) prox 1 activity (claims 1-5 and 79 in part as they recite activity).

Methods to measure the B-catenin/TCF pathway requiring: (i) APC gene mutations (claim 13 in part); (ii) B-catenin gene mutations (claim 13 in part); or (iii) nuclear localization of B-catenin (claim 13 in part).

The following claim(s) are generic: Claim 12 (with regard to measurement of the B-catenin/TCF pathway), Claims 15, 17, 21, 31, 33-38, 41, 46 (with regard to molecules that suppress prox-1).

5. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The different elements of the different species are structurally unique and do not share common structural elements that are related to functionality. For example, different molecules that may suppress prox-1 such as oligonucleotides or dominant negative proteins are composed of different subunits (i.e. nucleotides joined by phosphodiester bonds versus amino acids joined by peptide bonds) that adopt different three-dimensional structures and function differently in biological environments. Different screening methods require different analytical steps to determine the quantitative presence of expression analytes (such as mRNA or protein detection) as compared to detecting a quantitative measure of some particular biological activity.

Similarly, measurements of different gene mutations of biological element localization to establish B-catenin/TCF pathway activation are different at least in so far as the different genes are composed of unique nucleotide sequences and measurement of polypeptide localization requires analysis of polypeptides which are different that nucleic acids.

6. During a telephone conversation with Jennifer Flory on 01/13/2010 a provisional election was made with traverse to prosecute the invention of Group 1, claims 1-15 and 79, and the particular species of: prox 1 expression level, B-catenin/TCF signaling pathway, nuclear localization of B-catenin, and an inhibitor that is a dominant negative prox 1 or a dominant negative Prox-1 encoding nucleic acid. Affirmation of this election must be made by applicant in replying to this Office action. Claims 17, 21, 22, 25-29, 31, 33, 34, 36-38, 41, 46, 48, 52, 54, 55, 68 and 70-76 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

8. Claims 1, 11 and 13 are objected to because of the following informalities: Claims 1, 11, and 13 recite the gene symbols Prox-1 (claim 1), CD44, Enc1, and ID2

(claim 11) and APC (claim 13), where at the first instance of each gene symbol in the claims the symbol should be accompanied by the full gene name. For example, in claim 1, "measuring Prox-1 (prospero homeobox protein 1) expression or activity". Appropriate correction is required.

Claim Rejections - 35 USC § 112 2nd ¶ - Indefiniteness

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-15 and 79 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-15 and 79 are unclear over the stated purpose of the claimed methods as "screening colon tissue for a pathological condition" as stated in the preamble of claim 1. Claim 1 recites "wherein elevated Prox-1 expression or activity in the colon tissue correlates with a pathological phenotype", however there is no required method step where an "elevated Prox-1 expression or activity" is in fact detected. As such there is not a nexus between the recited purpose of the claimed method, the 'wherein clause', and the required method steps, and as such it is unclear how the performed method steps accomplish the stated purpose of the claimed method.

Claims 11-13 are unclear over recitation of the limitations stating "elevated Prox-1 expression or activity and elevated expression of the at least one gene" (claim 11) and "activation of the B-catenin/TCF pathway and elevated Prox-1 expression or activity"

(claims 12 and 13) correlate with a pathological phenotype. The instantly rejected claims depend from claim 1, which appears to require that elevated Prox-1 expression or activity, as a single measured parameter, correlates with a pathological phenotype. It is thus unclear if the claimed methods in fact require both elevated expression of the at least one gene (claim 11) or activation of the B-catenin/TCF pathway (claims 12 and 13) in addition to Prox-1 expression or activity to indicate the pathological phenotype, or if elevated Prox-1 expression or activity is sufficient in the claimed method to indicate a pathological phenotype.

Claim Rejections - 35 USC § 112 1st ¶ - Scope of Enablement

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 1-15 and 79 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for

> A method for determining an increased likelihood of the presence of colon cancer in a human subject suspected of having colon cancer, said method comprising:
> obtaining a sample of colon tissue from said subject;
> detecting an abundance of prox-1 (prospero homeobox protein 1) mRNA in said sample that is indicative of an elevated level of prox-1 expression, wherein said elevated level is statistically significantly increased as compared to the level of prox-1 expression in a population of colon tissue samples that do not have cancer; and
> correlating the presence of said elevated level of prox-1 expression in said sample with an increased likelihood of the presence of colon cancer in the subject

does not reasonably provide enablement for the methods as claimed which encompass any level of elevated expression or activity, diagnosis of any pathological condition in a colon tissue, analyses performed in any mammal, and detection of any analyte to measure prox-1 expression. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Nature of the invention and breadth of the claims

The claims are drawn to methods for detecting a pathological condition in colon tissue comprising analysis of prox-1 expression.

The claims encompass the detection of any level of elevated gene expression as compared to any level.

The claims encompass the detection of any pathological condition in any subject mammal.

The claims encompass the analysis of analyte for the determination of elevated gene expression.

The claims thus require knowledge of a correlation between any level of elevated gene expression according to any measured analyte, in any subject organism and the presence of any pathological condition.

Direction provided by the specification and working example

The instant specification provides an analysis of prox-1 mRNA expression in human colon cancer samples as compared to other tumor types and non-tumor controls. The specification teaches that prox-1 is significantly increased in colon tumor

samples as compared to non-cancer tissue (p.60 - Example 2). The instant specification does not provide any example of any pathological condition other than colon cancer tissue analysis.

The instant specification does not provide for any statistical or quantitative analysis of the expression of prox-1 protein in tissue samples (p.60-61) and teaches that some tumor samples did not show increased protein expression. The instant specification asserts that studies may be performed to measure if prox-1 protein correlates with prox-1 mRNA (p.75-76 – Example 11), but does not provide any evidence that such a correlation exists, or that prox-1 protein expression is diagnostically indicative of any colon pathology.

State of the art, level of skill in the art, and level of unpredictability

While the state of the art and level of skill in the art with regard to the analysis of gene expression in any sample is high, the unpredictability in associating any gene expression level with an condition, as generically encompassed by the claims, is higher.

Because the claims encompass the analysis of gene expression in any mammal, whereas the specification teaches only the statistical analysis of human samples, it is relevant to point out the unpredictability in extrapolating gene expression reults among different organisms. For example, Hoshikawa et al (2003) teaches unpredictability with regard to applying gene expression results among different organisms. The reference teaches the analysis of gene expression in lung tissue in response to hypoxic conditions which lead to pulmonary hypertension (Fig. 1). The reference teaches that the gene expression profile in mouse is different from that observed in rat (Tables 1-4; p.209 -

Abstract). Thus it is unpredictable as to whether or not any genes that are colon cancer-related in, for example, humans are in fact applicable to diagnosing any different pathological condition in any other non-human organism.

Because the claims encompass detecting any level of gene expression in a sample from an individual and comparing that level to any control level or average level to determine an elevated level that is indicative of rejection, it is relevant to point out the unpredictability associated with gene expression in any individual. Cheung et al (2003) teaches that there is natural variation in gene expression among different individuals. The reference teaches an assessment of natural variation of gene expression in lymphoblastoid cells in humans, and analyzes the variation of expression data among individuals and within individuals (replicates) (p.422, last paragraph; Fig 1). The data indicates that, for example, expression of ACTG2 in 35 individuals varied by a factor of 17; and that in expression of the 40 genes with the highest variance ratios, the highest and lowest values differed by a factor of 2.4 or greater (Fig 3). Similarly, the prior art of Shalon et al (2001) teaches that preferably 20-50 different test individuals are assayed to obtain meaningful data showing a significant change in gene expression levels, and changes of gene expression of at least 2 fold and up to 100 fold or more are desirable for the comparison of gene expression levels between a case and control population (p.10 ¶156, ¶158).

And while the claims encompass any analyte in the measure of gene expression (e.g.: activity, or protein levels), while the specification teaches only the significant association of mRNA levels with the presence of colon cancer, it is relevant to point out

that other measure of gene expression do not always correlate with mRNA levels. For example, Chen et al (2002) teaches that it is typical for protein abundances to not be correlated with mRNA abundances in tissue samples. It is thus unpredictable as to whether or not any non-mRNA analyte would in fact be predicative of mRNA expression.

Quantity of experimentation required

A large and prohibitive amount of experimentation would be required to make and use the claimed invention. Such experimentation would require case:control analysis of prox-1 gene expression from any organism of interest. Such experimentation would further require the analysis of different types of analytes and potential correlations with any pathological condition. Even if such experimentation were to be performed, there is no assurance that the any associations beyond those identified in the specification (i.e. elevated prox-1 mRNA expression in colon tissue as indicative of likelihood of colon cancer in humans) would be confirmed.

Conclusion

Taking into consideration the factors outlined above, including the nature of the invention and breadth of the claims, the state of the art, the level of skill in the art and its high level of unpredictability, the lack of guidance by the applicant and the particular examples, it is the conclusion that an undue amount of experimentation would be required to make and use the claimed invention in the full scope as encompassed by the claims.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

14. Claims 1-4, 7, 9, 10, 14 and 79 are rejected under 35 U.S.C. 102(a) as being anticipated by Parr et al (2003) (this reference was publicly available as of 7/17/2003).

Parr et al teaches that elevation of prox-1 mRNA in colon tissue as compared to normal colon mucosa is indicative of the presence of colon caner (e.g.: Fig 1 and 2; p.534 – Materials and methods; p.536 – Prox-1 and podoplanin were significantly increased in colon cancer and Prox-1 was linked with local invasion; Table III; p.538, left col. last paragraph). Thus Parr et al provides a method for screening colon tissue for a pathological condition meeting the limitations of claim 1, and teaches comprising sample tissue expression to healthy tissue (claim 2), obtaining a colon tissue sample (claim 3), identifying colon cancer tissue (claim 4), measuring prox-1 mRNA (claim 5), isolating mRNA (claim 9), performing QPCR (claim 10), and analysis of humans (claim 14).

Relevant to claim 79, Parr et al teaches the association of elevated prox-1 expression with colon cancer, and that the prox-1 marker offers prognostic value for colon cancer patients (e.g. p.538, left col., last paragraph), thus providing a diagnosis of colon cancer for samples wherein an elevated prox-1 expression level is detected.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Parr et al (2003) (this reference was publicly available as of 7/17/2003).

Parr et al teaches that elevation of prox-1 mRNA in colon tissue as compared to normal colon mucosa is indicative of the presence of colon caner (e.g.: Fig 1 and 2; p.534 – Materials and methods; p.536 – Prox-1 and podoplanin were significantly increased in colon cancer and Prox-1 was linked with local invasion; Table III; p.538, left col. last paragraph). Thus Parr et al provides a method for screening colon tissue for a pathological condition meeting the limitations of claim 1, from which rejected claim 15 depends.

Parr et al does not teach a step of administering to a subject a composition comprising a prox-1 inhibitor.

However, Parr et al does teach that the over-expressed factors identified by Parr et al, such as prox-1, may represent a target for therapeutic strategies (p.538, left col. last paragraph).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have administered to a colon cancer subject that over expresses prox-1 a compound that inhibits prox-1. The skilled artisan would have

recognized that Parr et al teaches that over expression of prox-1 is required for colon cancer development, and thus the skilled artisan would recognize that using prox-1 as a therapeutic target, as taught by Parr et al, would include use of compounds that inhibit the over expressed element.

17. Claims 8 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parr et al (2003) as applied to claim 15 above, and further in view of Rockman et al (2001).

Parr et al teaches all of the limitations of claim 1, from which rejected claims 8 and 11-13 depend.

Parr et al does not teach mRNA measurement by in situ hybridization (claim 8), analysis of ID2 expression (claim 11), or measuring B-catenin/TCF activation (claim 12) by nuclear localization of B-catenin (claim 13). However, such methods in the analysis of colon cancer were well known in the art at the time the invention was made.

Rockman et al teaches the analysis of mRNA expression using in situ hybridization (e.g. o.45113 – In situ hybridization), the overexpression of ID2 in colon cancer cells (e.g. p.45113 – Abstract), B-catenin/TCF activation in colon cancer cells (e.g. p.45113 – Abstract), and that B-catenin/TCF activation can be indicated by nuclear localization of B-catenin (e.g. p.45115, right col., third full paragraph).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have used the in situ hybridization methods of Rockman et al for the analysis of prox-1 expression as taught by Parr et al. The skilled artisan

would have been motivated to use the in situ hybridization methods of Rockman et al because the skilled artisan would have recognized that such methods represent alternative methods that can successfully identify gene expression levels.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have used other indicators of the presence of colon cancer, such as ID2 over expression, B-catenin/TCF activation and nuclear localization of B-catenin, as taught by Rockman et al, in the colon cancer detection methods of Parr et al. The skilled artisan would have been motivated to use additional indicators of colon cancer, as taught by Rockman et al because the skilled artisan would recognize that the inclusion of additional measured parameters in a screening method would make the screening more robust and reliable.

Conclusion

18. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Kapushoc whose telephone number is 571-272-3312. The examiner can normally be reached on Monday through Friday, from 8am until 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached at 571-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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/Stephen Kapushoc/
Primary Examiner, Art Unit 1634